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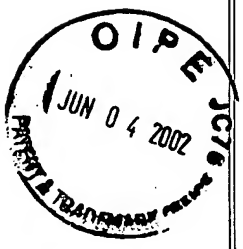

PATENT
Customer No. 22,852
Attorney Docket No. 08203.0018

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:	)	
	)	
Frank BONADIO et al.	)	
	)	
Application No.: 10/092,528	)	Group Art Unit: 3739
	)	
Filed: March 8, 2002	)	Examiner: Unknown
	)	
For: COLONIC OVERTUBE	)	

Assistant Commissioner for Patents
Washington, DC 20231

Sir:

CLAIM FOR PRIORITY

Under the provisions of Section 119 of 35 U.S.C., Applicants hereby claim the benefit of the filing date of Ireland Patent Application Number 2001/0220, filed March 8, 2001, and Ireland Patent Application Number 2001/0916, filed October 18, 2001, for the above-identified United States Patent Application.

In support of Applicants' claim for priority, certified copies of the priority applications are filed herewith.

Respectfully submitted,

FINNEGAN, HENDERSON, FARABOW,
GARRETT & DUNNER, L.L.P.

Dated: June 4, 2002

By: _____
Roland G. McAndrews
Reg. No. 41,450

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I HEREBY CERTIFY that annexed hereto is a true copy of documents filed in connection with the following patent application:

Application No.	2001/0220
Date of Filing	8 March 2001
Applicant	ATROPOS LIMITED, an Irish Company of Unit 4, Sunnybank Centre, Bray, County Wicklow, Ireland.

Dated this 6 day of February 2002.

An officer authorised by the
Controller of Patents, Designs and Trademarks.

FORM NO. 1

▷ 010220

REQUEST FOR THE GRANT OF A PATENT

PATENTS ACT, 1992

The Applicant(s) named herein hereby request(s)

___X___ the grant of a patent under Part II of the Act

_____ the grant of a short-term patent under Part III of the Act on the basis of the information furnished hereunder.

1. Applicant(s)

Name: ATROPOS LIMITED
Address: Unit 4
Sunnybank Centre
Bray
County Wicklow
Ireland

Description/Nationality

An Irish Company

2. Title of Invention

"A Device"

3. Declaration of Priority on basis of previously filed application(s) for same invention (Sections 25 & 26)

Previous filing date	Country in or for which filed	Filing No.

4. Identification of Inventor(s)
Name(s) of person(s) believed by Applicants(s) to be the inventor(s)

Name: Frank Bonadio, a citizen of the United States of America.
Address: 2 Martello Terrace, Bray, County Dublin, Ireland.

Name: Edmund Brennan, an Irish citizen.
Address: 14 The Willows, Monkstown Valley, County Dublin, Ireland.

Name: John Butler, an Irish citizen.
Address: 16 Holly Park, Blackrock, County Dublin, Ireland.

5. Statement of right to be granted a patent (Section 17(2) (b)

The Applicant derives the rights to the Invention by virtue of a Deed of Assignment dated March 7, 2001.

6. Items accompanying this Request – tick as appropriate

(i)	X	Prescribed filing fee (£100.00)
(ii)	X	Specification containing a description and claims
	_____	Specification containing a description only
	X	Drawings referred to in description or claims
(iii)	_____	An abstract
(iv)	_____	Copy of previous application (s) whose priority is claimed
(v)	_____	Translation of previous application whose priority is claimed
(vi)	X	Authorisation of Agent (this may be given at 8 below if this Request is signed by the Applicant (s))

7. Divisional Application (s)

The following information is applicable to the present application which is made under Section 24 –

Earlier Application No: .....

Filing Date: .....

8. Agent

The following is authorised to act as agent in all proceedings connected with the obtaining of a patent to which this request relates and in relation to any patent granted -

Name	Address
John A. O'Brien & Associates	The address recorded for the time being in the Register of Patent Agents, and currently Third Floor, Duncairn House, 14 Carysfort Avenue, Blackrock, Co. Dublin, Ireland.

9. Address for Service (if different from that at 8)

As above

Signed _____ JOHN A. O'BRIEN & ASSOCIATES

Date March 8, 2001

"A DEVICE"

Introduction

The invention relates to a device to assist in the passage of a colonoscope or other endoscopic instrument through the colon to access any point in the colon, and in particular to access any point in the colon distally of the descending colon.

Modern colonoscopes consist of a control section attached to a long flexible shaft with a steerable tip. The flexible shaft carries several tubes for light, air, water and suction. Light is transmitted through non-coherent fibre-optic bundles and images are transmitted from a miniature CCD TV camera positioned on the tip of the colonoscope. In some cases a biopsy channel with a larger bore to allow therapeutic procedures to be performed is also provided.

A control mechanism is used to steer the colonoscope through the colon using control wheels at the proximal external end of the device. There are usually two wheels, one for lateral control, and another for vertical control. These control wheels are attached to guide wires that extend through and are attached to the tip of the colonoscope. The colonoscope is typically 100-150 centimetres long and must be pushed from the distal end and guided through tortuous passages using external manipulation. Torque may be applied to the colonoscope to assist in advancing it through bends in the colon.

The lower gastrointestinal tract comprises the rectum and the large intestine or colon. The colon, in a textbook arrangement of its anatomy, extends upwards from the lower right quadrant, traverses the width of the body just below the

diaphragm, travels downwards along the left side of the abdomen and then loops in an anterior retrograde manner before linking up with the rectum and the anus. Even in such a textbook arrangement, the large intestine is difficult to cannulate with a colonoscope due to the flexible nature of the shaft of the instrument and the floppy nature of the colon. This is even more difficult with the more realistic anatomies of actual people. In some people the sigmoid colon can be very long and is unfixed, except by its mesentery, and so can be extremely difficult to cannulate due to its predisposition to form loops when a colonoscope is pushed through it. Some anatomical landmarks, such as the recto-sigmoidal junction, the splenic flexure and the hepatic flexure, are also difficult to pass through simply because of their tortuous nature. Looping of the colonoscope within the sigmoid colon and transverse colon exacerbates the problems in traversing these areas.

Normally the act of inserting the colonoscope through the sigmoid colon or transverse colon causes them to stretch out their floppy redundant sections. A loop often forms, the size of which is limited only by the degree to which the mesentery will stretch. The presence of a loop often reduces the ability of the endoscopist to proceed much further through the colon. Attempts to pass through the splenic flexure will often simply cause the sigmoid loop to increase in size, stretch the mesentery and cause considerable pain and discomfort to the patient. In a similar manner, attempts to pass the hepatic flexure will often cause a transverse loop to increase in size with resulting pain and discomfort. The loop can sometimes be removed by making the redundant bowel contract into a shorter segment, like the bellows of an accordion or concertina, giving the walls of the floppy section of colon a corrugated appearance. This is accomplished by several techniques known to those skilled in the art of lower GI endoscopy. Unfortunately, further pushing of the colonoscope into the colon can cause the loops to re-form.

In view of these problems it is not surprising that colonoscopy is a difficult technique that can only be mastered after performing many hundreds of examinations. The ability to speedily cannulate the bowel and traverse the entire colon all the way to the caecum is a skill that is only enjoyed by a minority of endoscopists. Published research on the subject of difficulty encountered in colonoscopy shows that the procedure fails in up to 15% of cases where failure is defined as inability to reach or visualise the caecum. Up to 35% of cases are considered to be difficult as defined by extended duration of the procedure and experience of pain by the patient. Other research shows that up to 29% of cases are considered to be technically difficult.

In addition, in certain colonoscopic procedures, for example multiple polypectomy, it is necessary to insert and remove a colonoscope several times. This requires considerable skill and takes a considerable length of time.

There is therefore a need for a device which will facilitate a colonoscopy to be performed more easily and more efficiently.

Statements of the Invention

According to the invention there is provided a colonic cannula comprising an overtube, the overtube defining an inner lumen extending therethrough through which a colonoscope may be received, and the overtube being extendable between a first shortened configuration and a second elongated configuration for cannulating a colon to a point distally of the descending colon.

In one embodiment of the invention in the first shortened configuration at least a portion of the overtube is concertinaed and in the second elongated configuration the portion of the overtube is flattened out.

Preferably the overtube comprises at least one corrugation for kink resistance during advancement of the cannula through the colon.

The at least one corrugation may extend substantially circumferentially around the overtube.

The at least one corrugation may extend helically around the overtube.

According to the invention there is also provided a colonic cannula comprising an overtube, the overtube defining an inner lumen extending therethrough through which a colonoscope may be received, at least portion of the overtube being flexible or pliable.

Desirably the overtube comprises at least one corrugation.

The at least one corrugation may extend substantially circumferentially around the overtube.

The at least one corrugation may extend helically around the overtube.

In a preferred embodiment of the invention the overtube defines a plurality of inner lumena for exchange of external devices and/or fluids.

In one embodiment the cannula comprises means for viewing the colon from externally of the colon, the viewing means being at least partially received in one or more inner lumena. Ideally the viewing means is a video camera system.

In another embodiment the cannula comprises means for insufflating the colon, one or more inner lumena providing an insufflation channel.

In a further embodiment the cannula comprises means for flushing the colon, one or more inner lumena providing a flushing channel.

In yet another embodiment of the invention the cannula comprises means for illuminating the colon, the illumination means being at least partially received in one or more inner lumena.

In a preferred embodiment of the invention the cannula comprises a connecting means anchored to a distal end of the overtube for advancing the cannula over the colonoscope by activation of the connecting means from externally of the colon. Ideally the connecting means is a drawstring attached to the overtube distal end for looping through a working channel in the colonoscope to a point externally of the colon.

The cannula preferably comprises limiting means to prevent complete insertion of the overtube into the colon. Ideally the limiting means comprises a flange at a proximal end of the overtube.

In another aspect the invention provides an apparatus for carrying out a colonoscopy comprising:-

a colonic cannula of the invention;

a colonoscope; and

a guide device, the guide device comprising an elongate tubular sheath, the sheath defining a lumen through which the colonoscope may be received, and means to engage the sheath with the colonoscope received within the lumen.

In one embodiment of the invention the engagement means is releasable. Preferably the guide device defines a distal end, and the engagement means is provided at the distal end.

The engagement means may comprise an inflatable tube, the tube having an inflation port for inflation of the tube from an uninflated insertion configuration for insertion into and withdrawal from a colon to an inflated gripping configuration for gripping the colonoscope received within the lumen, and the tube being attached to the sheath. Preferably the inflation port has a connection means for connection to a supply of inflation fluid. Ideally the engagement means includes a fastener of resilient material which is releasable on inflation of the tube. The fastener is preferably a band.

The engagement means may comprise a drawstring. Preferably the drawstring is threaded back through the guide device and/or the colonoscope received within the lumen to facilitate proximal manipulation thereof.

The engagement means may comprise an adhesive tape.

The engagements means may be of a hook-and-pile material.

According to a further aspect of the invention there is provided a method for carrying out a colonoscopy comprising the steps of :-

providing a colonoscope and a colonic cannula;

introducing the colonoscope into a colon and advancing the colonoscope to the descending colon;

reducing the sigmoid colon into an accordioned configuration;

advancing the cannula over the colonoscope to the descending colon to cannulate the sigmoid colon;

advancing the colonoscope to a point distally of the descending colon;

advancing the cannula over the colonoscope to a point distally of the descending colon; and

withdrawing the colonoscope and the cannula from the colon.

In one embodiment of the invention the colonoscope is withdrawn from the colon before withdrawing the cannula from the colon. Preferably the method comprises the step of advancing an endoscopic instrument through the cannula to access a point in the colon distally of the descending colon after withdrawal of the colonoscope.

The endoscopic instrument may be a polypectomy instrument.

The endoscopic instrument may be a colonoscope.

In a preferred embodiment the cannula is mounted to the colonoscope before introduction of the colonoscope into the colon.

In another embodiment of the invention the cannula is advanced by extending the cannula from a shortened configuration to an elongated configuration.

The cannula may be at least partially advanced by pushing the cannula from externally of the colon. Preferably the cannula comprises a connecting means anchored to a distal end of the cannula, and the cannula is at least partially advanced by activation of the connecting means from externally of the colon. Ideally the connecting means is a drawstring attached to the cannula distal end, the drawstring being looped through a working channel in the colonoscope to a point externally of the colon, and the drawstring is pulled from externally of the colon to at least partially advance the cannula.

The colonoscope may be advanced to any point in the colon as far as the caecum.

The cannula may be advanced to any point in the colon as far as the caecum.

In a preferred embodiment the method comprises the steps of :-

providing a guide device, the guide device being mounted to the colonoscope during introduction and advancement of the colonoscope to the descending colon; and

at least partially withdrawing the guide device from the colon after advancing the cannula between the colonoscope and the guide device to the descending colon.

In another embodiment of the invention the method comprises the steps of engaging the guide device with the colonoscope, and pulling the guide device taut before advancing the cannula between the colonoscope and the guide device. Preferably the guide device is releasably engaged to the colonoscope, and the method comprises the step of releasing the engagement means to allow the guide device to move relative to the colonoscope. Ideally the guide device is releasably engaged to the colonoscope by inflation of a portion of the guide device.

In a further embodiment of the invention the guide device is releasably fastened to the colonoscope adjacent a distal end of the colonoscope before introduction of the colonoscope into the colon to prevent the guide device from slipping off the colonoscope during insertion. Preferably the method comprises the step of releasing the fastening means upon actuation of the engagement means. Ideally a portion of the guide device is inflated to release the fastening means and actuate the engagement means.

The method may comprise the step of at least partially insufflating the colon.

The method may comprise the step of at least partially flushing the colon.

The method may comprise the step of illuminating the colon.

Brief Description of the Drawings

The invention will be more clearly understood from the following description of some embodiments thereof given by way of example only, in which:-

Fig. 1 is a schematic view of the major components of the large intestine, rectum and anus;

Fig. 2 is a part cross sectional view of a colonic cannula according to the invention in a shortened configuration partially inserted into a colon over a colonoscope;

Figs. 3 and 4 are part cross sectional views of the cannula and colonoscope of Fig. 2 illustrating straightening of the transverse colon and advancement of the colonoscope respectively;

Fig. 5 is a part cross sectional view of the cannula of Fig. 2 in an elongated configuration over the colonoscope;

Fig. 6 is a part cross sectional view of the cannula of Fig. 5 after withdrawal of the colonoscope;

Fig. 7 is a part cross sectional view of the cannula of Fig. 6 with an instrument inserted through the cannula;

Fig. 8 is a perspective view of a distal end of the cannula of Fig. 2;

Figs. 9 to 11 are perspective views of a guide device for use with a colonic cannula according to the invention;

Fig. 12 is a part cross sectional view of the guide device of Fig. 9 partially inserted into a colon over a colonoscope and inflated;

Fig. 13 is a perspective view of the guide device of Fig. 12 in use;

Fig. 14 is a perspective view of the guide device of Fig. 12 and a colonic cannula according to the invention; and

Figs. 15 to 20 are part cross sectional views of the guide device and the cannula of Fig. 14 in use.

Detailed Description

Figure 1 illustrates the major components of the large intestine, rectum and anus. The anus A leads into the rectum B which in turns leads into the sigmoid colon C having a mesentery. From the sigmoid colon C a start D leads to the descending colon E which leads to the splenic flexure F. The transverse colon G leads from the splenic flexure F and is attached to the mesentery H and terminates at the hepatic flexure I which leads into the ascending colon J terminating in the caecum K to which the appendix L is attached. The ascending and descending sections of the colon J, E are generally fixed in position while the transverse and sigmoid portions G, C are partially mobile and are attached to mesenteries H and N. The redundancy in the sigmoid colon C can be seen. Two relatively acute bends exist between the transverse colon G and the descending E and ascending J sections and are referred to as the splenic F and hepatic I flexures respectively.

Referring to Figs. 2 to 8 and Figs. 14 to 20 there is illustrated a colonic cannula according to the invention, the cannula comprising an overtube 100. The overtube 100 defines an inner lumen 104 extending therethrough through which a colonoscope 2 may be received, and the overtube 100 is extendable between a first shortened configuration, as illustrated in Figs. 2 to 4, and a second elongated configuration, as illustrated in Figs. 5 to 7, for cannulating a colon to a point distally of the descending colon E.

In this case the overtube 100 is polymeric, and a proximal end 101 of the overtube 100 has a concertina-type configuration in the first shortened configuration (Fig. 2), and a flattened out configuration in the second elongated configuration (Fig. 5).

It will be appreciated that extension of the overtube 100 may be achieved in a number of ways, for example additional sections may be attached to the overtube 100 as required, in a manner similar to the extension of a chimney sweeping brush.

Referring to Fig. 8 a distal end 102 of the overtube 100 is shown in more detail. The overtube 100 defines a plurality of circumferential inner lumena 105, 106, 107 extending through the overtube 100, as well as the main inner lumen 104 through which the colonoscope 2 is received.

The main lumen 104 typically has a diameter of approximately 15 mm which results in a significantly larger cross sectional area than that of a typical colonoscope working channel.

The circumferential lumena 105, 106, 107 can be used for exchange of external devices or fluids, for example for flushing the colon with water, and/or for

insufflation of the colon, for example to blow a protruding piece of colon laterally to clear a path for safe advancement of the overtube 100 through the colon.

Alternatively or additionally the circumferential lumena 105, 106, 107 can be used to provide a channel through which means for illuminating the colon can be passed, and/or to provide a channel through which means for viewing the colon from externally of the colon can be passed, for example a video camera system. It is highly advantageous to advance the overtube 100 with a visible path distal of the overtube 100 to ensure no bowel is trapped at the distal end 102 of the overtube 100 during advancement through the colon.

In use, the overtube 100 is mounted to the colonoscope 2 in the shortened configuration before introduction of the colonoscope 2 into the colon. The colonoscope 2 is advanced through the sigmoid colon C until its distal end is in the descending colon E. The sigmoid colon C is then reduced to a straightened accordioned configuration in the manner known to those skilled in the art. The overtube 100 is then partially advanced into the colon over the colonoscope 2 until the distal end 102 is at the start of the descending colon E. The proximal end 101 of the overtube 100 is still in the shortened configuration after the initial insertion into the colon. The overtube 100 acts as a splint and will maintain the sigmoid colon C in the straightened, reduced, accordioned configuration.

The colonoscope 2 may therefore be easily advanced through the transverse colon G to the hepatic flexure I (Fig.2). The transverse colon G is straightened in the normal manner as routinely performed by those skilled in the art (Fig.3), and the colonoscope 2 is further advanced as far distally as the caecum K (Fig.4).

The proximal end 101 of the overtube 100 is then extended from the shortened, concertinaed configuration to the lengthened, flattened out configuration, as required, thereby advancing the overtube 100 distally over the colonoscope 2 through the descending colon E and the transverse colon G until the distal end 102 reaches any desired point of interest in the colon as far distally as the caecum K (Fig. 5).

The proximal end 101 of the overtube 100 is extended by pushing the overtube 100 distally from externally of the colon. Alternatively or additionally a connecting means, for example a drawstring, may be passed distally through the colonoscope working channel out of a distal end of the colonoscope 2, and attached to the distal end 102 of the overtube 100. By maintaining the position of the colonoscope 2 and pulling proximally on the connecting means from externally of the colon the distal end 102 of the overtube 100 can be advanced over the colonoscope 2 thereby extending the proximal end 101 of the overtube 100.

The overtube 100 acts as a colonic cannula and maintains in a straightened and reduced configuration those sections of the colon that are normally mobile such as the simoid colon C and the transverse colon G. This gives the colon the classic question mark configuration as shown in Fig. 5. The colonoscope 2 may therefore be removed through the main lumen 104 from the colon leaving the overtube 100 in place in the cannulated colon (Fig. 6). The overtube 100 can then be used to facilitate insertion of an endoscopic instrument through the overtube 100, for example an instrument 103 to remove polyps from the ascending colon J (Fig. 7), or the overtube 100 can be used to facilitate reinsertion of the colonoscope 2.

If a subsequent region of interest in the colon is proximally or distally of the initial region of interest, the overtube 100 can be shortened or elongated until the distal end 102 is at the subsequent region of interest. While shortening or withdrawal of the colonic cannula may be achieved by simply withdrawing the cannula from the colon, advancement or lengthening of the colonic cannula is preferably achieved with the colonoscope in situ.

When the colonoscope 2 has been removed from the overtube 100, the overtube 100 provides a large working channel through the colon through which any instrument may be quickly and easily passed to access any point in the colon as far distally as the caecum K. Rapid and less painful exchange of instruments and/or colonoscopes is facilitated by the overtube 100 because there is no contact between the instruments/colonoscopes and the inner wall of the colon during insertion or withdrawal of the instruments/colonoscopes.

In addition, the colonic cannula has a much larger diameter than the diameter of a typical colonoscope working channel. Thus, larger instruments may be used during a surgical procedure with the colonic cannula. Larger samples may also be removed using the colonic cannula.

The overtube 100 is removed from the colon by collapsing the proximal end 101 to the shortened configuration and withdrawing the overtube 100 proximally out of the colon. Alternatively if the colonoscope 2 has been removed from the colon, the overtube 100 may be pulled proximally from the colon. It is not necessary to reintroduce the colonoscope 2 into the colon to facilitate removal of the overtube 100.

Alternatively the overtube 100 can be withdrawn from the colon leaving the colonoscope 2 in place in the colon. In this case the colonoscope 2 can be

subsequently withdrawn from the colon thereby enabling the entire colon to be examined during withdrawal of the colonoscope 2.

The overtube 100 may comprise a flange at the proximal end 101 to prevent complete insertion of the overtube 100 into the colon.

Referring to Figs. 9 to 19 there is illustrated a guide device 82, suitable for use with the colonic cannula according to the invention to assist with and speed up the advancement of the overtube 100 over the colonoscope 2 to the decending colon E. Fig. 9 illustrates the guide device 82, mounted over the colonoscope 2. The guide device 82 comprises a tubular sheath 80 with an inflatable clamp section 81 for engaging the guide device 82 with the colonoscope 2 attached to a distal end of the sheath 80. The clamp section 81 is short relative to the tubular sheath 80. An inflation port 83 is provided extending proximally of the sheath 80 and in communication with the clamp section 81. The uninflated clamp section 81 is initially fixed to the colonoscope 2 by a distal fixation mechanism, the fixation mechanism, in this case, being provided by a wide elasticated band 61 encapsulating the leading edge of the guide device 82 and the colonoscope 2 (Fig. 9). Upon inflation of the clamp section 81, the proximal part of the wide elasticated band 61 rolls towards the tip of the colonoscope 2 (Fig. 10). When the clamp section 81 is fully inflated the elasticated band 61 rolls off the end of the clamp section 81 and disengages from the clamp section 81 (Fig. 11). The uninflated clamp section 71 may also be initially fixed to the colonoscope 2 by some other means such as double-sided adhesive tape or hook-and-pile material.

It will be appreciated that the distal fixation mechanism could also be provided by a drawstring threaded back through the colonoscope 2 to facilitate proximal manipulation of the fixation mechanism.

In use, the guide device 82 is mounted to the colonoscope 2 before introduction of the colonoscope 2 to the colon. The colonoscope 2 is then advanced to the descending colon E and the sigmoid colon C is reduced as described previously. The clamp section 81 is inflated to release the elasticated band 61 and engage the colonoscope 2. Fig. 12 shows the guide device 82 mounted over the colonoscope 2, and inserted into the reduced, accordioned sigmoid colon C with the clamp section 81 in the inflated configuration. A portion of the sheath 80 extends externally of the patient. An annular flange may be formed at the proximal end of the sheath 80 to prevent complete insertion of the guide device 82 into the colon.

The overtube 100 is advanced over the colonoscope 2, as illustrated in Fig. 14. By manually pulling the sheath 80 taut from a point external of the colon, easier passage of the overtube 100 over the colonoscope 2 and into the guide device 82 is achieved, as illustrated in Fig. 13. The inflated clamp section 81 firmly grips the colonoscope 2, thereby preventing the entire guide device 82 being pulled out of the colon as a clinician pulls the sheath 80 taut.

The overtube 100 is advanced over the colonoscope 2 (Fig. 15), into the sheath 80 of the guide device 82 (Fig. 16), until the distal end 102 of the overtube 100 abuts the inflated clamp section 81 (Fig.17), while maintaining the sheath 80 taut. The clamp section 81 is then deflated through the inflation port 83 so that it no longer grips the colonoscope 2 (Fig. 18), and the guide device 82 is at least partially withdrawn proximally over the overtube 100 and the colonoscope 2, so that the distal end of the guide device 82 is proximal of the distal end 102 of the overtube 100 (Fig. 19).

It will be appreciated that the overtube 100 may or may not be formed with a flange at its proximal end 101. In the case of no flange the overtube 100 will be formed sufficiently long to prevent complete insertion into the colon.

When the guide device 82 has been partially removed the colonoscope 2 is advanced distally through the descending colon E, through the splenic flexure F and into the transverse colon G to any point as far distally as the caecum K, as described previously with reference to Figs. 2 to 4.

As illustrated in Fig. 20 the overtube 100 isolates the colonoscope from the inner wall of the sigmoid colon C, and the passage of the colonoscope 2 through the splenic flexure F is thus eased. The overtube 90 acts as a splint and maintains the sigmoid colon C in the reduced, accordioned configuration.

The proximal end 101 of the overtube 100 may then be extended from the shortened, concertinaed configuration to the lengthened, flattened out configuration, as described previously with reference to Fig. 5, to cannulate the colon to any desired point as far distally as the caecum K.

In another embodiment of the invention, the colonic cannula comprises an overtube, the overtube defining an inner lumen extending therethrough through which a colonoscope 2 may be received. At least portion of the overtube is flexible or pliable for kink resistance during advancement of the cannula through the colon. In this case the overtube has at least one corrugation. The corrugation may be provided by a plurality of corrugated bands extending circumferentially around the overtube. During advancement of the cannula over the colonoscope 2 the corrugated bands prevent kinking of the overtube. This is particularly advantageous when the cannula is being advanced through a sharply

bent portion of the colon, for example when advancing the cannula through the splenic or hepatic flexures F, I, or through parts of the sigmoid colon C.

Alternatively or additionally, the at least one corrugation may be provided by one or more bands extending helically around the overtube. Such a convoluted overtube can be cheaply and quickly manufactured by, for example, an extrusion process.

It will be appreciated that corrugations may also be provided on the overtube 100, described previously with reference to Figs. 2 to 8 and Figs. 14 to 20, for resistance to kinking during advancement of the overtube 100 through the colon.

The cannula provides a bridge between the fixed rectum and the fixed descending colon over the floppy sigmoid colon, thus preventing loops from reforming in the sigmoid colon. Furthermore, the cannula provides a bridge between the fixed descending colon and the fixed ascending colon over the floppy transverse colon, thus preventing loops from reforming in the transverse colon. Thus advancement of the colonoscope through the colon as far as the caecum K is easier and quicker, and causes less discomfort to the patient.

The guide device enables a stiffening overtube to be advanced over a colonoscope inserted into a straightened, accordioned sigmoid colon without engaging the inner wall of the colon. In this manner friction between the overtube and the colon wall is eliminated. The inflated clamp section maintains the guide device at the distal end of the colonoscope during insertion of the overtube, even when tension is applied to pull the sheath taut.

The cannula according to the invention provides an ergonomic and easily workable means of cannulating the colon as far distally as the caecum, without requiring a long, awkward length of tubing externally of the colon.

In addition, corrugations on the overtube ensure that the cannula is resistant to kinking during advancement of the cannula through the colon.

The guide device and the stiffening overtube apparatus provides a means of cannulating the colon. The guide device and stiffening overtube apparatus could also be applied to cannulate other body lumena, in which medical instruments are to be inserted.

The invention is not limited to the embodiments hereinbefore described which may be varied in detail.

Claims

1. A colonic cannula comprising an overtube, the overtube defining an inner lumen extending therethrough through which a colonoscope may be received, and the overtube being extendable between a first shortened configuration and a second elongated configuration for cannulating a colon to a point distally of the descending colon.

2. A cannula as claimed in claim 1 wherein in the first shortened configuration at least a portion of the overtube is concertinaed and in the second elongated configuration the portion of the overtube is flattened out.

3. A cannula as claimed in claim 1 or 2 wherein the overtube comprises at least one corrugation for kink resistance during advancement of the cannula through the colon.

4. A cannula as claimed in claim 3 wherein the at least one corrugation extends substantially circumferentially around the overtube.

5. A cannula as claimed in claim 3 wherein the at least one corrugation extends helically around the overtube.

6. A colonic cannula comprising an overtube, the overtube defining an inner lumen extending therethrough through which a colonoscope may be received, at least portion of the overtube being flexible or pliable.

7. A cannula as claimed in claim 6 wherein the overtube comprises at least one corrugation.

8. A cannula as claimed in claim 7 wherein the at least one corrugation extends substantially circumferentially around the overtube.

9. A cannula as claimed in claim 7 wherein the at least one corrugation extends helically around the overtube.

10. A cannula as claimed in any preceding claim wherein the overtube defines a plurality of inner lumena for exchange of external devices and/or fluids.

11. A cannula as claimed in claim 10 wherein the cannula comprises means for viewing the colon from externally of the colon, the viewing means being at least partially received in one or more inner lumena.

12. A cannula as claimed in claim 11 wherein the viewing means is a video camera system.

13. A cannula as claimed in any of claims 10 to 12 wherein the cannula comprises means for insufflating the colon, one or more inner lumena providing an insufflation channel.

14. A cannula as claimed in any of claims 10 to 13 wherein the cannula comprises means for flushing the colon, one or more inner lumena providing a flushing channel.

15. A cannula as claimed in any of claims 10 to 14 wherein the cannula comprises means for illuminating the colon, the illumination means being at least partially received in one or more inner lumena.

16. A cannula as claimed in any preceding claim wherein the cannula comprises a connecting means anchored to a distal end of the overtube for advancing the cannula over the colonoscope by activation of the connecting means from externally of the colon.

17. A cannula as claimed in claim 16 wherein the connecting means is a drawstring attached to the overtube distal end for looping through a working channel in the colonoscope to a point externally of the colon.

18. A cannula as claimed in any preceding claim wherein the cannula comprises limiting means to prevent complete insertion of the overtube into the colon.

19. A cannula as claimed in claim 18 wherein the limiting means comprises a flange at a proximal end of the overtube.

20. A colonic cannula substantially as hereinbefore described with reference to the accompanying drawings.

21. Apparatus for carrying out a colonoscopy comprising:-

a colonic cannula as claimed in any of claims 1 to 20;

a colonoscope; and

a guide device, the guide device comprising an elongate tubular sheath, the sheath defining a lumen through which the

colonoscope may be received, and means to engage the sheath with the colonoscope received within the lumen.

22. Apparatus as claimed in claim 21 wherein the engagement means is releasable.

23. Apparatus as claimed in claim 21 or 22 wherein the guide device defines a distal end, and the engagement means is provided at the distal end.

24. Apparatus as claimed in any of claims 21 to 23 wherein the engagement means comprises an inflatable tube, the tube having an inflation port for inflation of the tube from an uninflated insertion configuration for insertion into and withdrawal from a colon to an inflated gripping configuration for gripping the colonoscope received within the lumen, and the tube being attached to the sheath.

25. Apparatus as claimed in claim 24 wherein the inflation port has a connection means for connection to a supply of inflation fluid.

26. Apparatus as claimed in claim 24 or 25 wherein the engagement means includes a fastener of resilient material which is releasable on inflation of the tube.

27. Apparatus as claimed in claim 26 wherein the fastener is a band.

28. Apparatus as claimed in any of claims 21 to 23 wherein the engagement means comprises a drawstring.

29. Apparatus as claimed in claim 28 wherein the drawstring is threaded back through the guide device and/or the colonoscope received within the lumen to facilitate proximal manipulation thereof.

30. Apparatus as claimed in any of claims 21 to 23 wherein the engagement means comprises an adhesive tape.

31. Apparatus as claimed in any of claims 21 to 23 wherein the engagement means is of a hook and pile material.

32. Apparatus for carrying out a colonoscopy substantially as hereinbefore described with reference to the accompanying drawings.

33. A method for carrying out a colonoscopy comprising the steps of :-

providing a colonoscope and a colonic cannula;

introducing the colonoscope into a colon and advancing the colonoscope to the descending colon;

reducing the sigmoid colon into an accordioned configuration;

advancing the cannula over the colonoscope to the descending colon to cannulate the sigmoid colon;

advancing the colonoscope to a point distally of the descending colon;

advancing the cannula over the colonoscope to a point distally of the descending colon; and

withdrawing the colonoscope and the cannula from the colon.

34. A method as claimed in claim 33 wherein the colonoscope is withdrawn from the colon before withdrawing the cannula from the colon.

35. A method as claimed in claim 34 wherein the method comprises the step of advancing an endoscopic instrument through the cannula to access a point in the colon distally of the descending colon after withdrawal of the colonoscope.

36. A method as claimed in claim 35 wherein the endoscopic instrument is a polypectomy instrument.

37. A method as claimed in claim 35 wherein the endoscopic instrument is a colonoscope.

38. A method as claimed in any of claims 33 to 37 wherein the cannula is mounted to the colonoscope before introduction of the colonoscope into the colon.

39. A method as claimed in any of claims 33 to 38 wherein the cannula is advanced by extending the cannula from a shortened configuration to an elongated configuration.

40. A method as claimed in any of claims 33 to 39 wherein the cannula is at least partially advanced by pushing the cannula from externally of the colon.

41. A method as claimed in any of claims 33 to 40 wherein the cannula comprises a connecting means anchored to a distal end of the cannula, and the cannula is at least partially advanced by activation of the connecting means from externally of the colon.

42. A method as claimed in claim 41 wherein the connecting means is a drawstring attached to the cannula distal end, the drawstring being looped through a working channel in the colonoscope to a point externally of the colon, and the drawstring is pulled from externally of the colon to at least partially advance the cannula.

43. A method as claimed in any of claims 33 to 42 wherein the colonoscope is advanced to any point in the colon as far as the caecum.

44. A method as claimed in any of claims 33 to 43 wherein the cannula is advanced to any point in the colon as far as the caecum.

45. A method as claimed in any of claims 33 to 44 comprising the steps of :-

providing a guide device, the guide device being mounted to the colonoscope during introduction and advancement of the colonoscope to the descending colon; and

at least partially withdrawing the guide device from the colon after advancing the cannula between the colonoscope and the guide device to the descending colon.

46. A method as claimed in claim 45 comprising the steps of engaging the guide device with the colonoscope, and pulling the guide device taut before advancing the cannula between the colonoscope and the guide device.

47. A method as claimed in claim 46 wherein the guide device is releasably engaged to the colonoscope, and the method comprises the step of releasing the engagement means to allow the guide device to move relative to the colonoscope.

48. A method as claimed in claim 46 or 47 wherein the guide device is releasably engaged to the colonoscope by inflation of a portion of the guide device.

49. A method as claimed in any of claims 45 to 48 wherein the guide device is releasably fastened to the colonoscope adjacent a distal end of the colonoscope before introduction of the colonoscope into the colon to prevent the guide device from slipping off the colonoscope during insertion.

50. A method as claimed in claim 49 comprising the step of releasing the fastening means upon actuation of the engagement means.

51. A method as claimed in claim 50 wherein a portion of the guide device is inflated to release the fastening means and actuate the engagement means.

52. A method as claimed in any of claims 33 to 51 comprising the step of at least partially insufflating the colon.

53. A method as claimed in any of claims 33 to 52 comprising the step of at least partially flushing the colon.

54. A method as claimed in any of claims 33 to 53 comprising the step of illuminating the colon.

55. A method for carrying out a colonoscopy substantially as hereinbefore described with reference to the accompanying drawings.

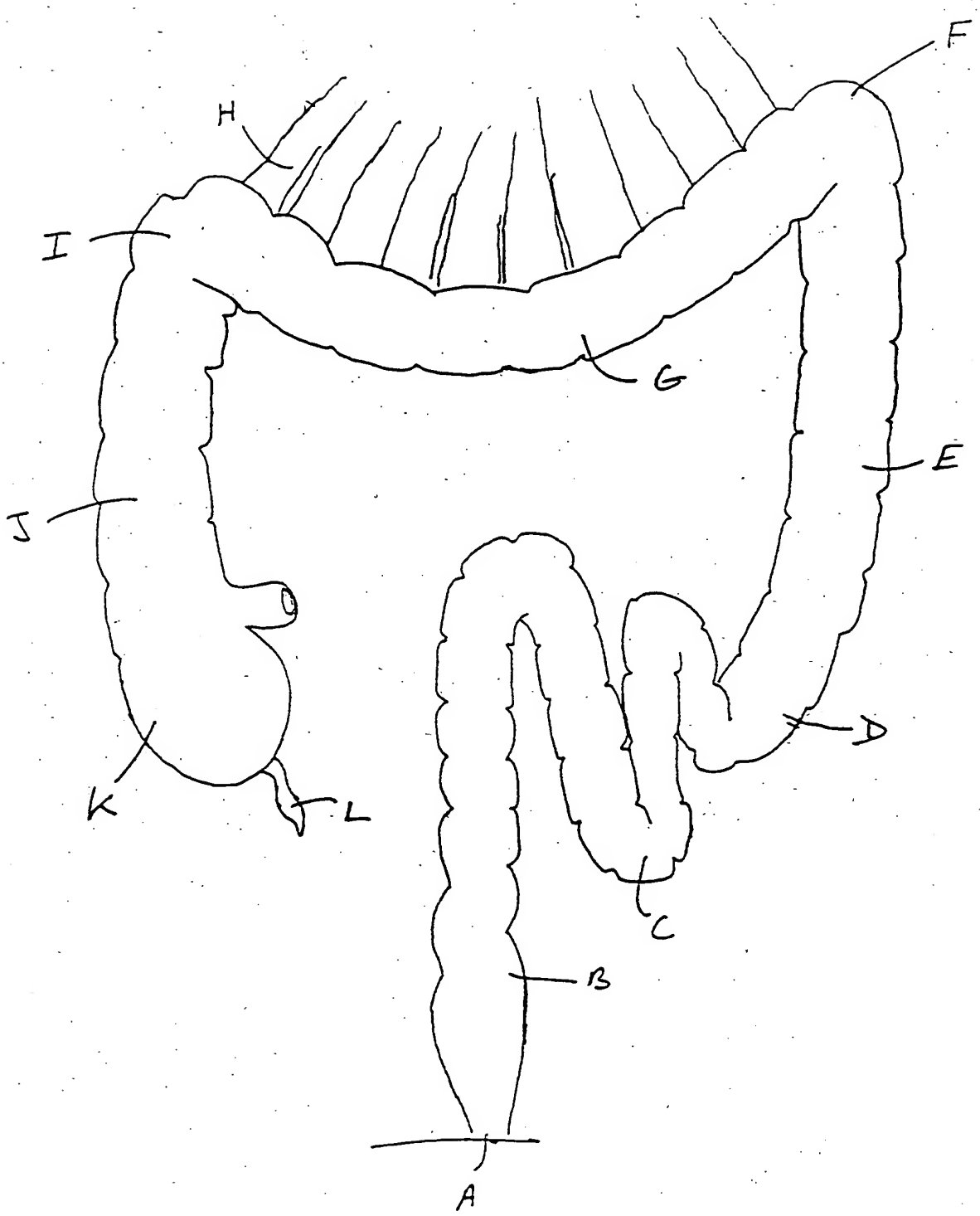

FIG 1.

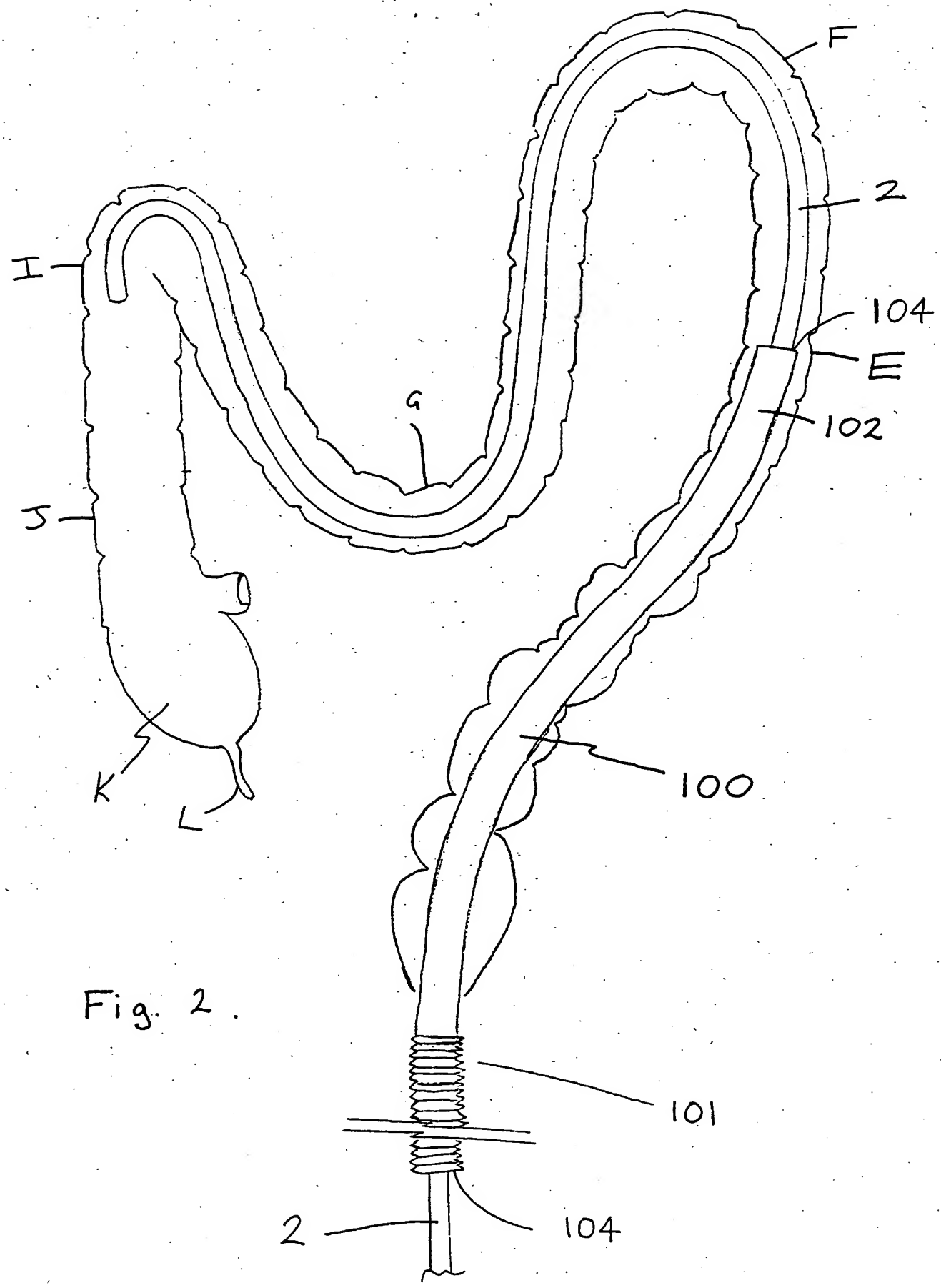

Fig. 2.

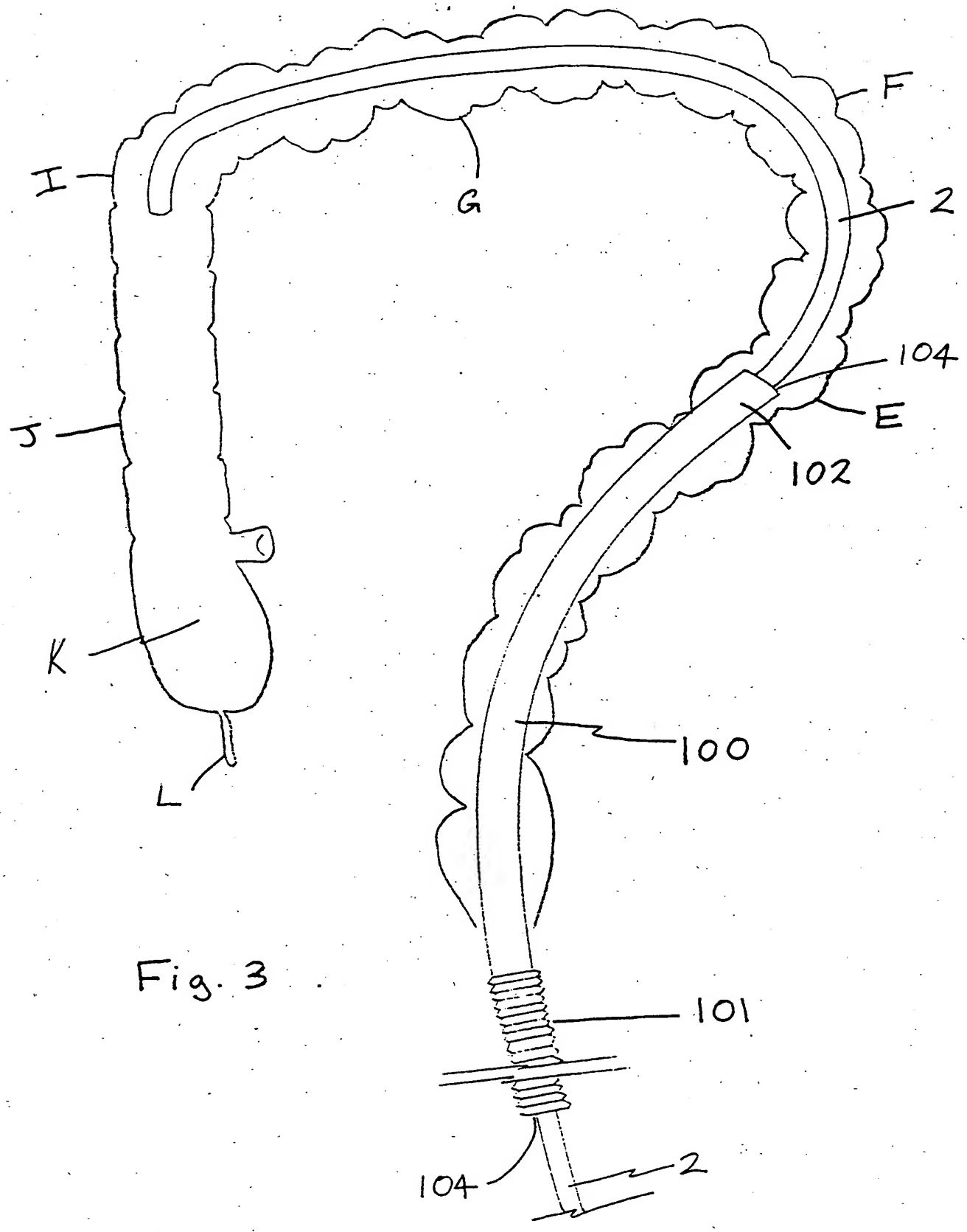

Fig. 3

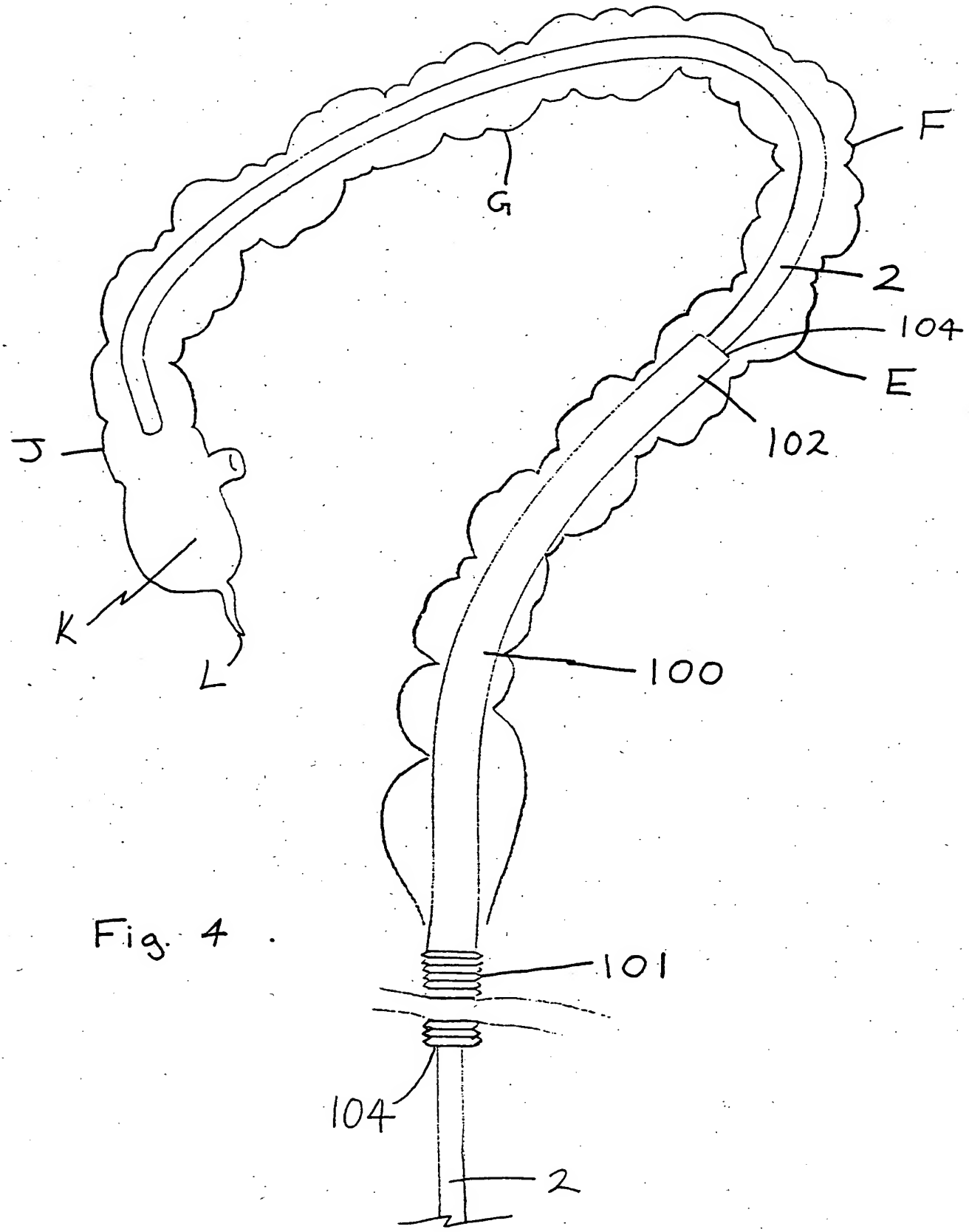

Fig. 4

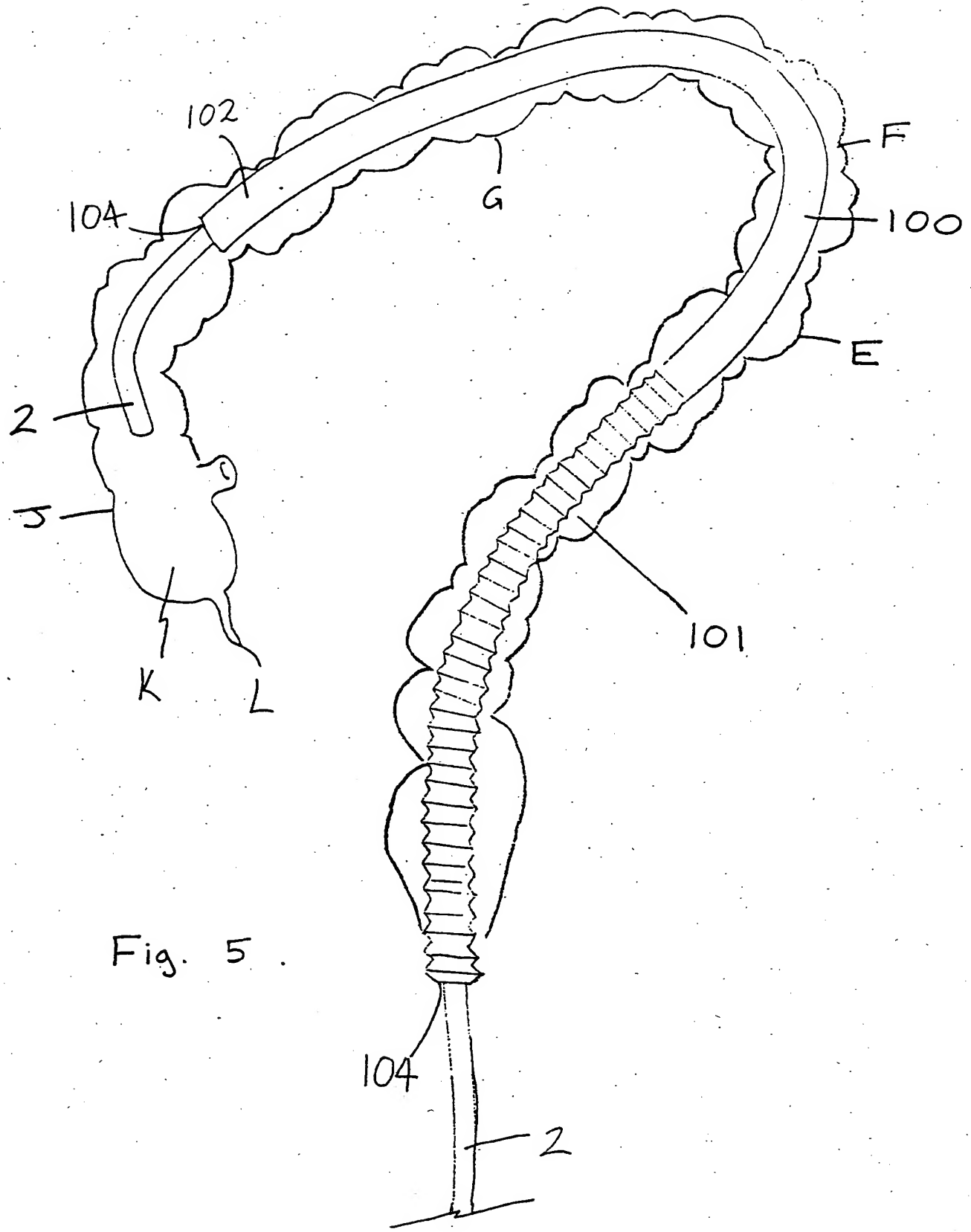

Fig. 5.

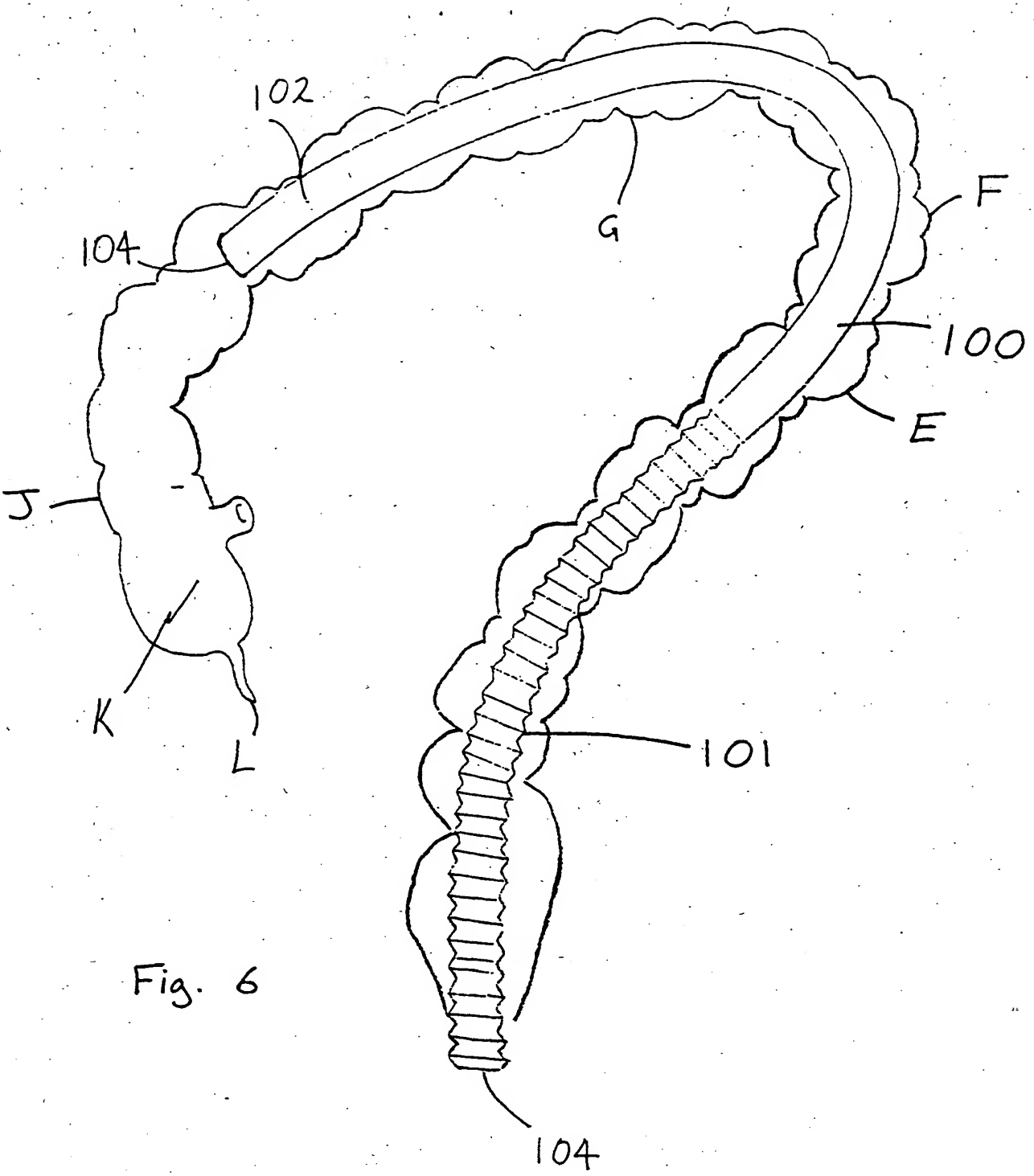

Fig. 6

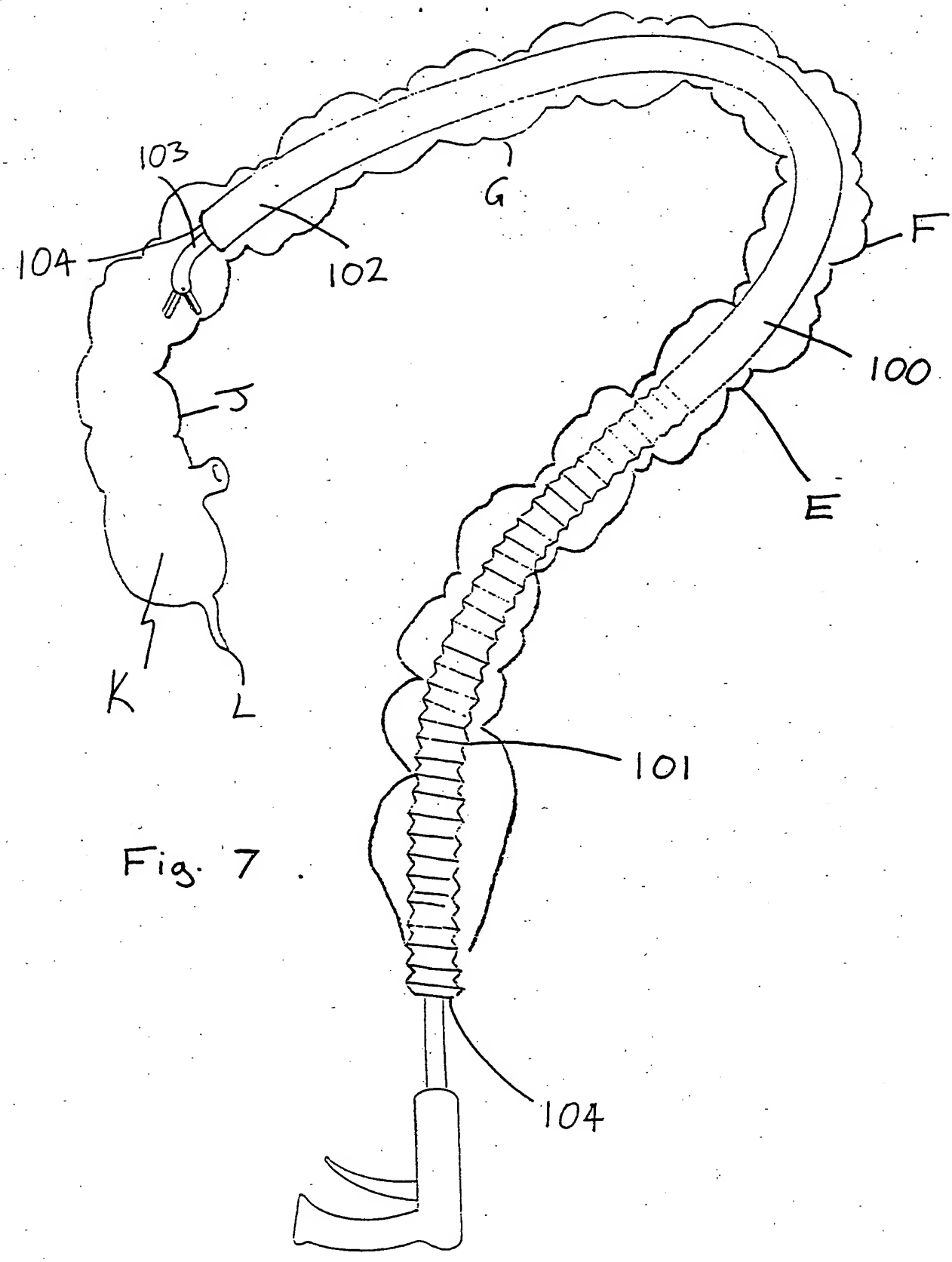

Fig. 7.

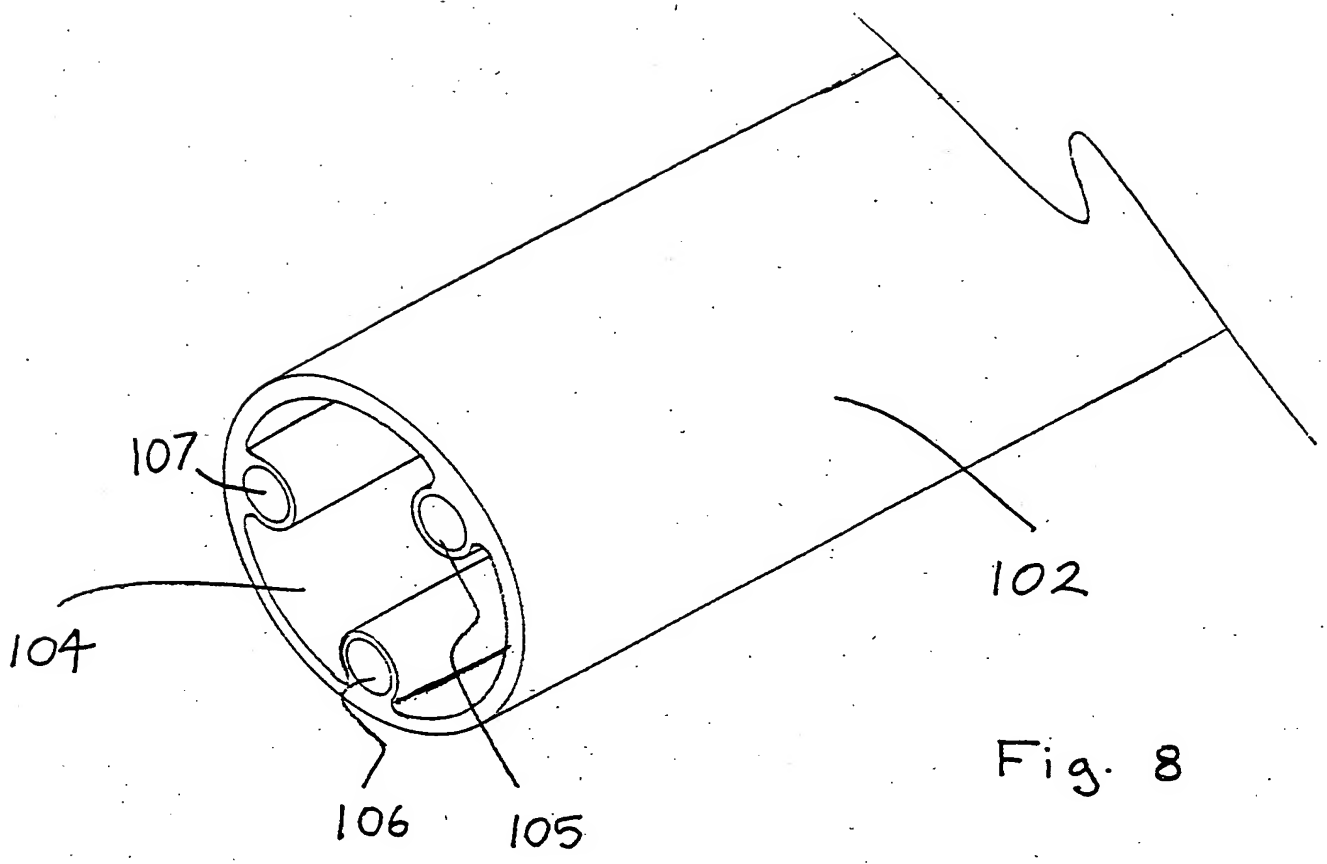

Fig. 8

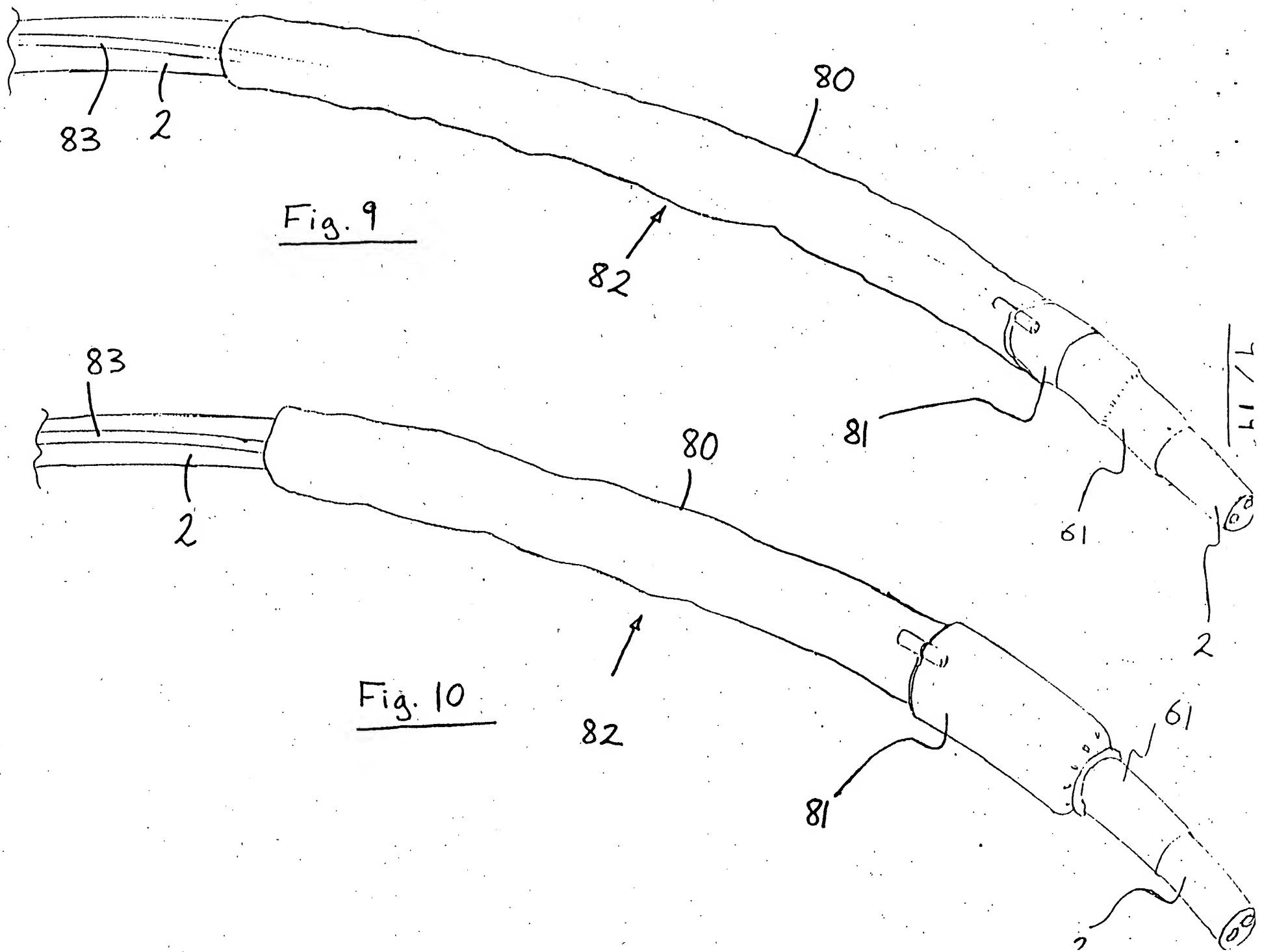

Fig. 9

Fig. 10

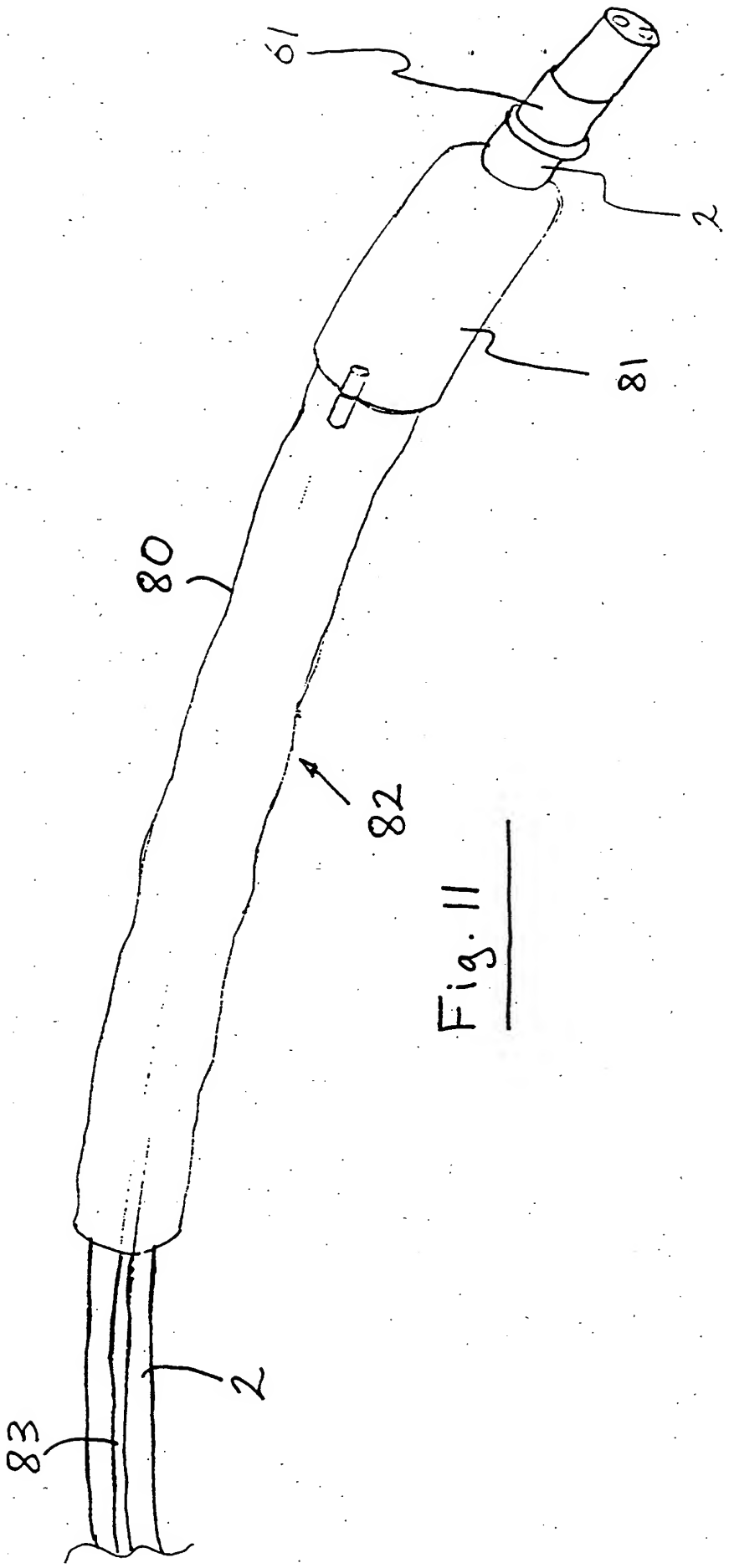

Fig. 11

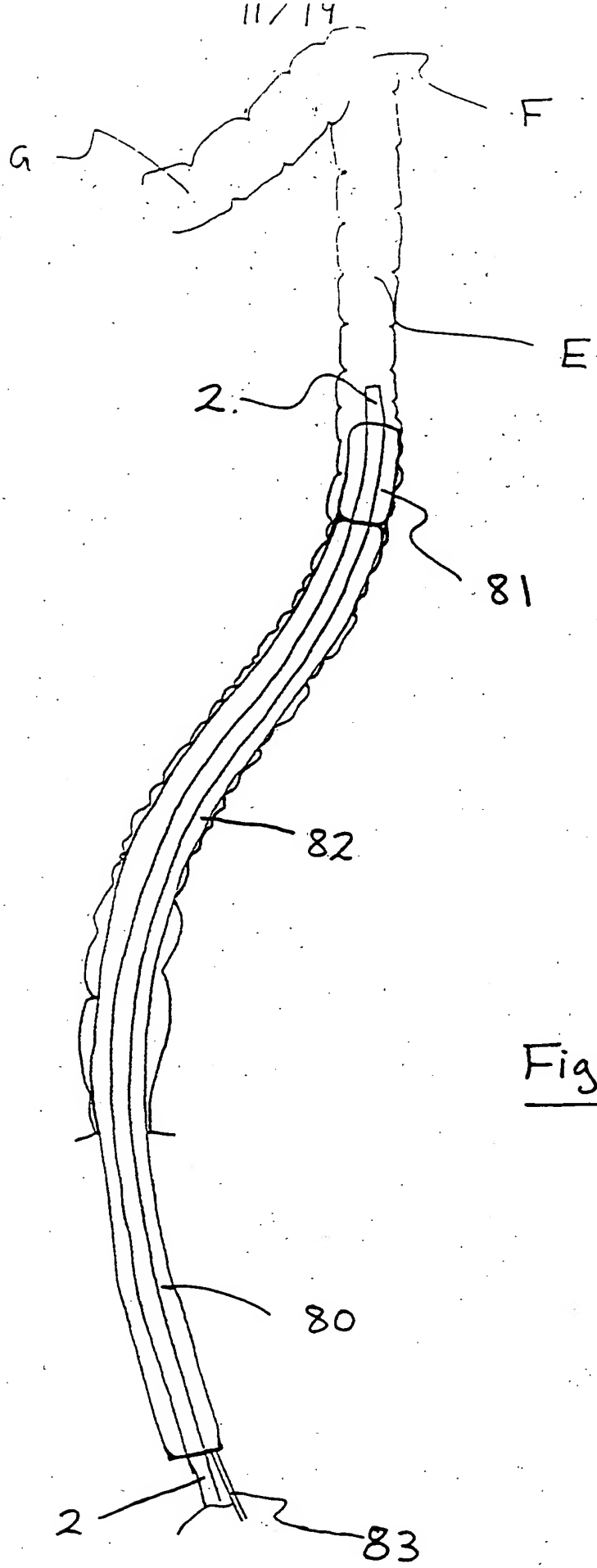

Fig. 12

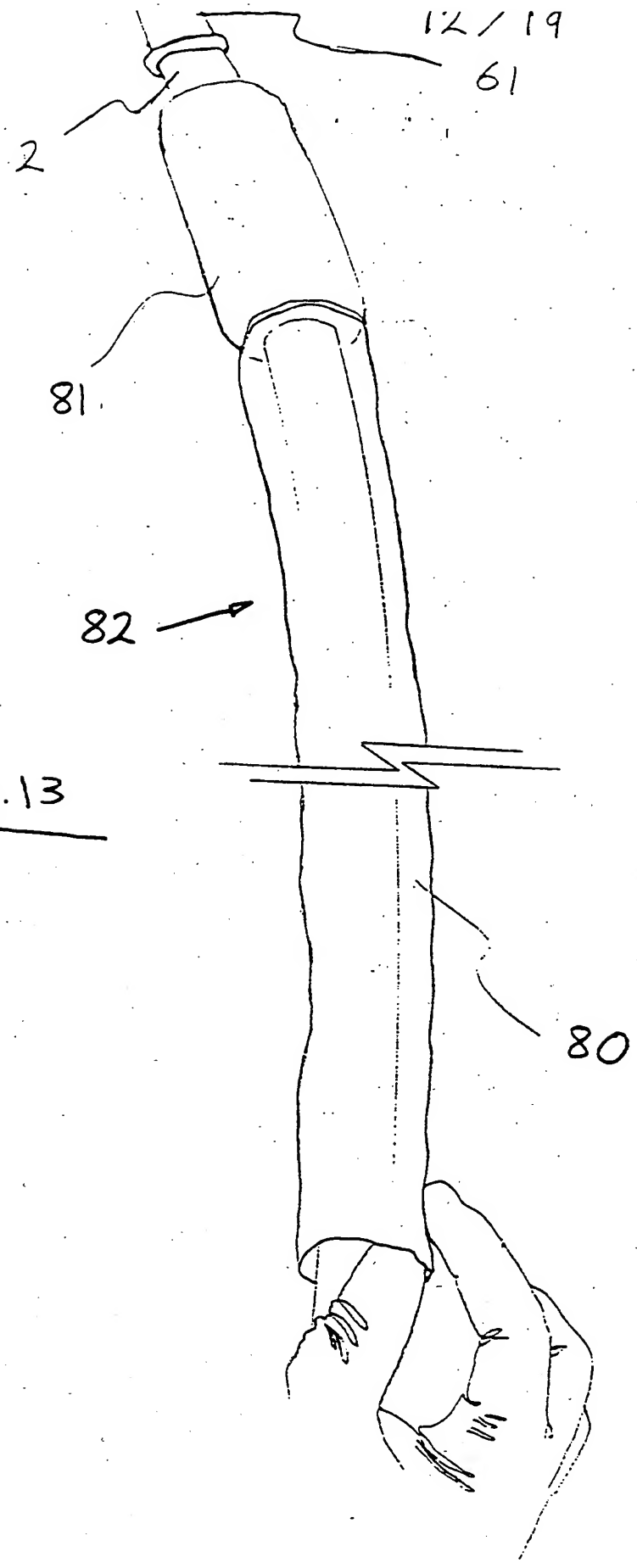

Fig. 13

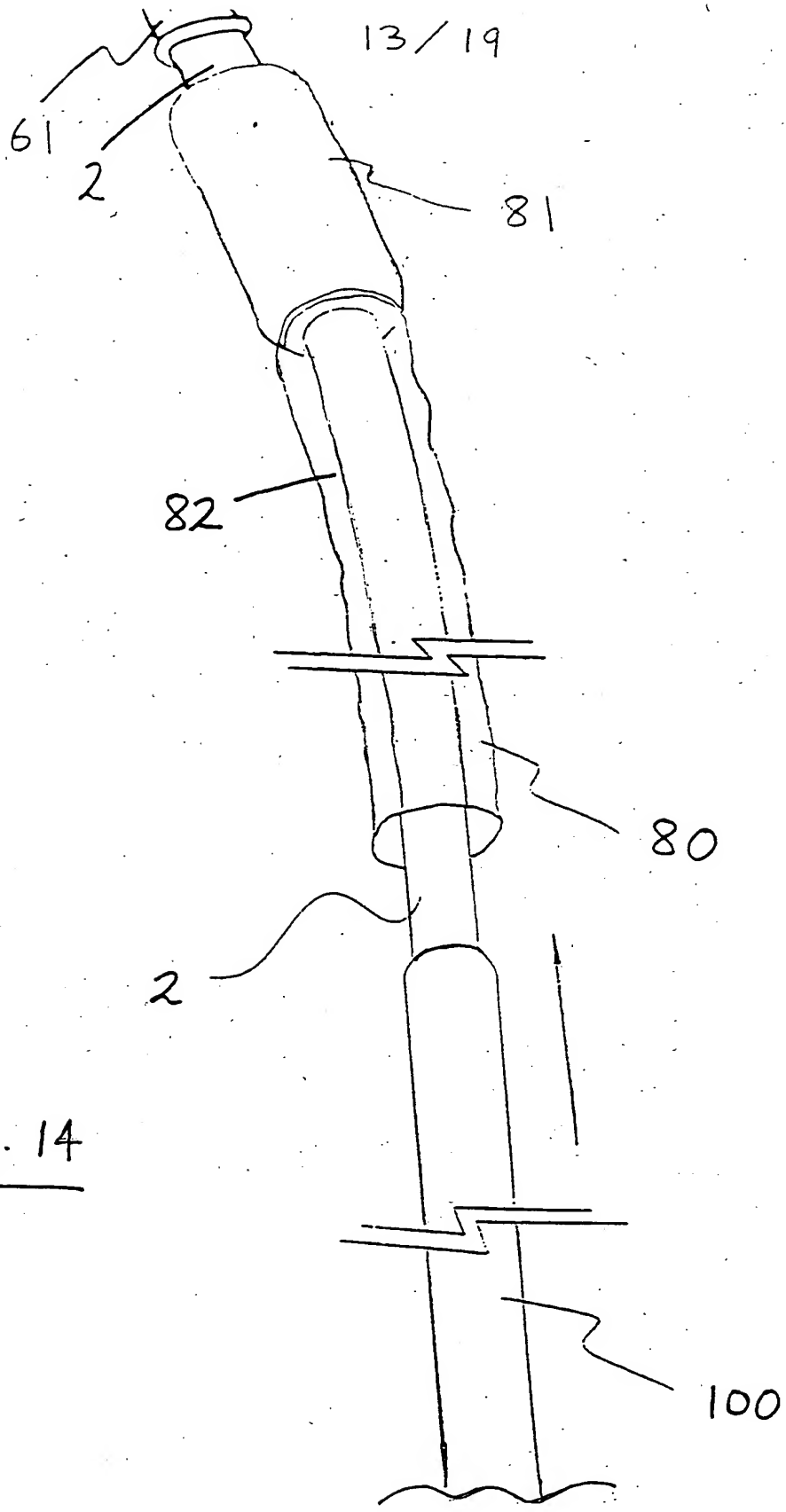

Fig. 14

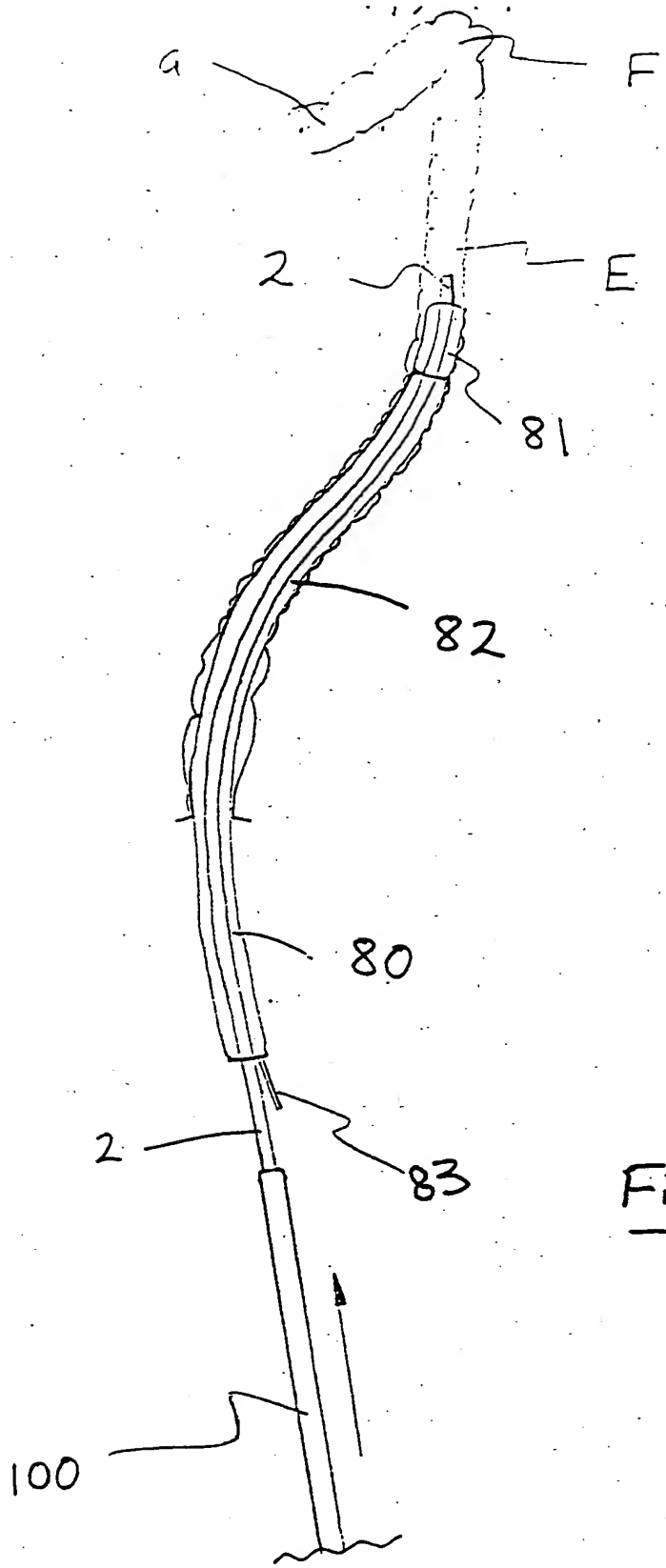

Fig. 15

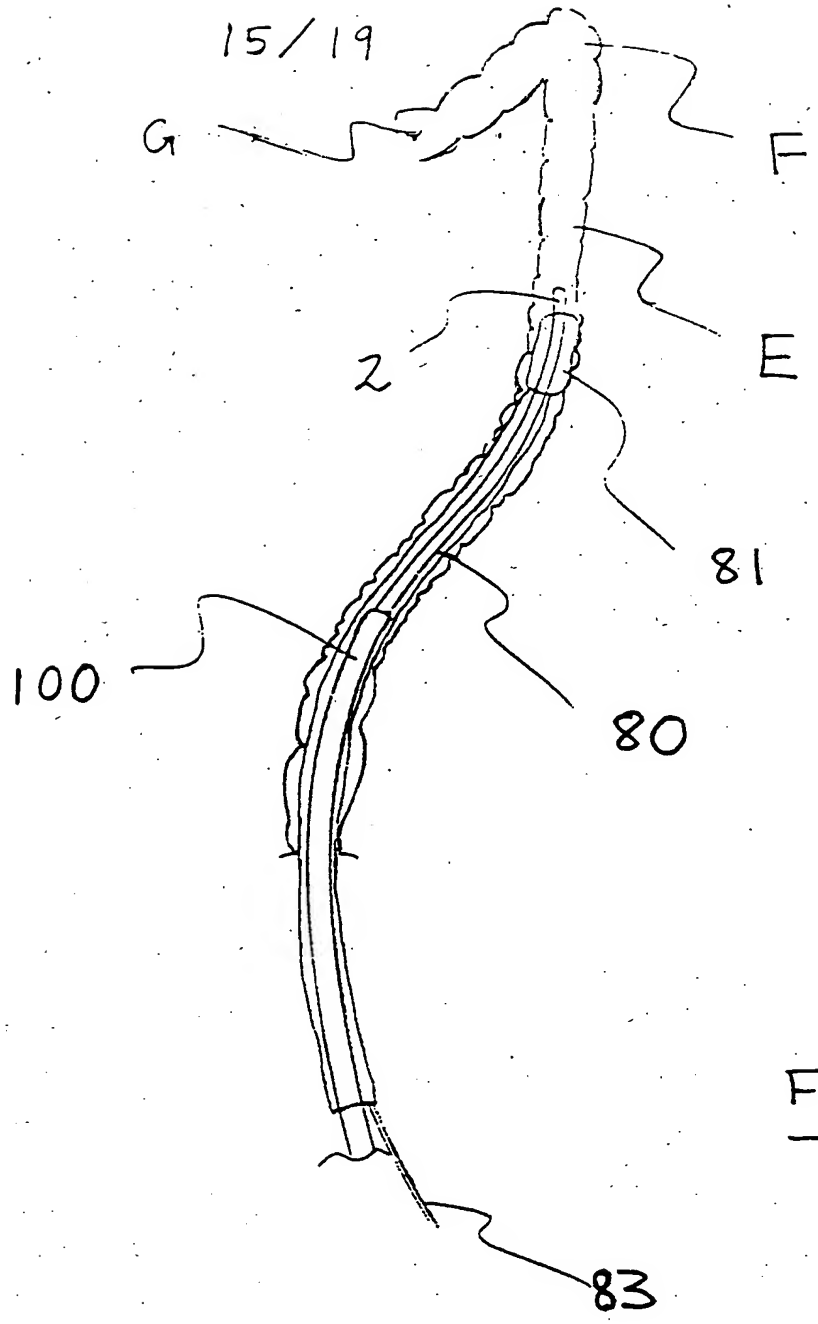

Fig. 16

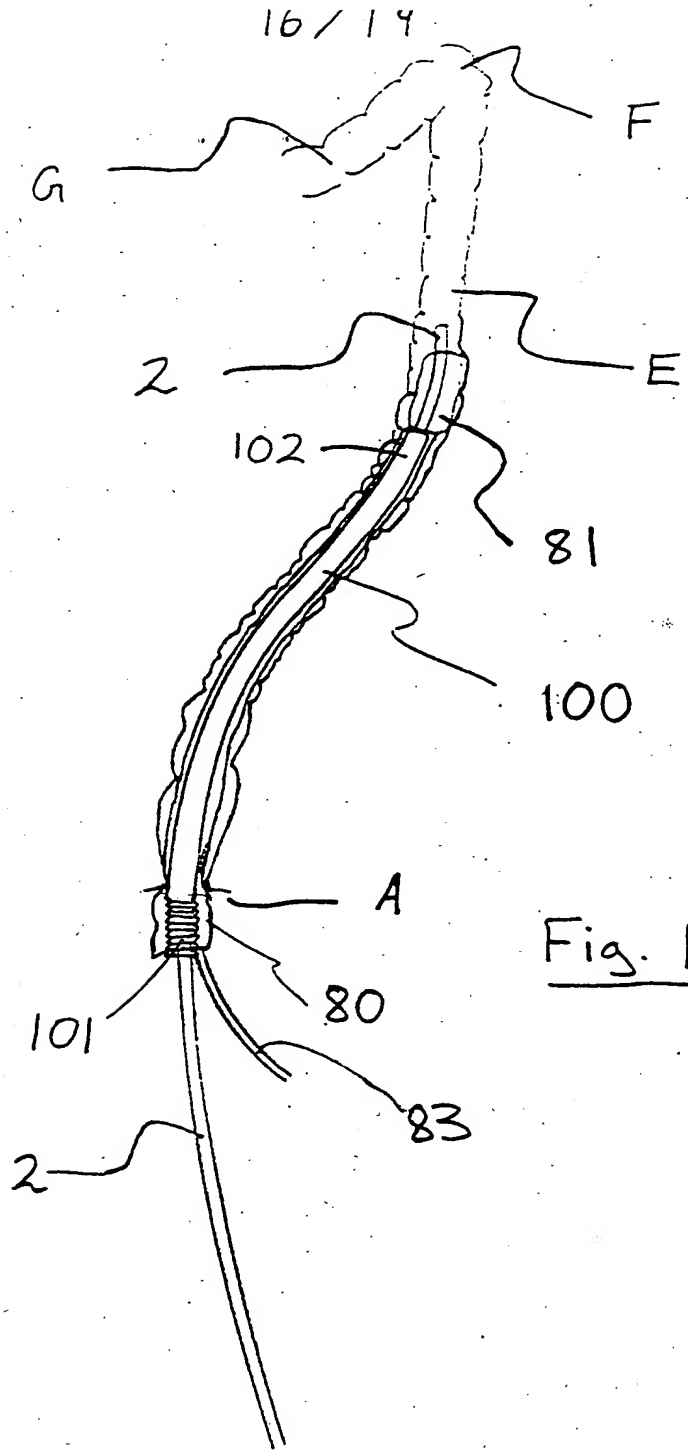

Fig. 17

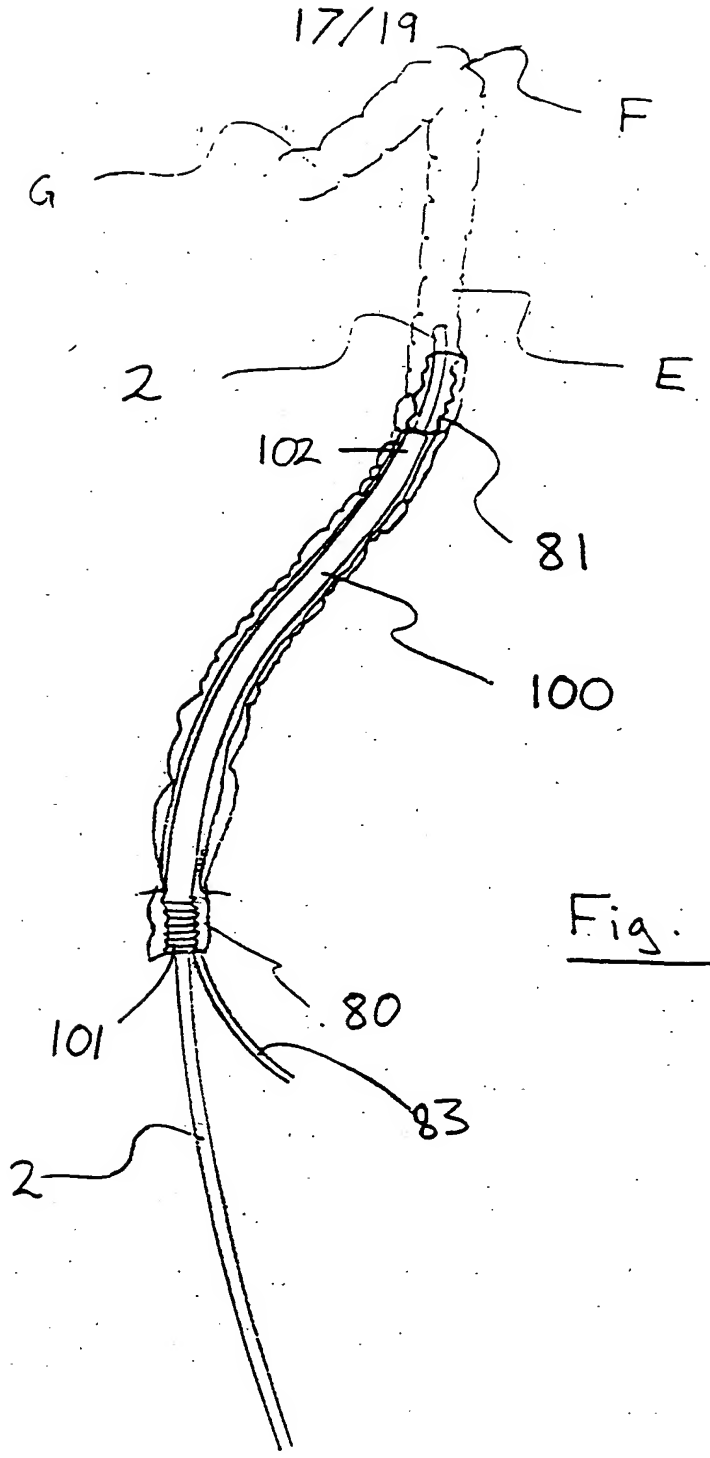

Fig. 18

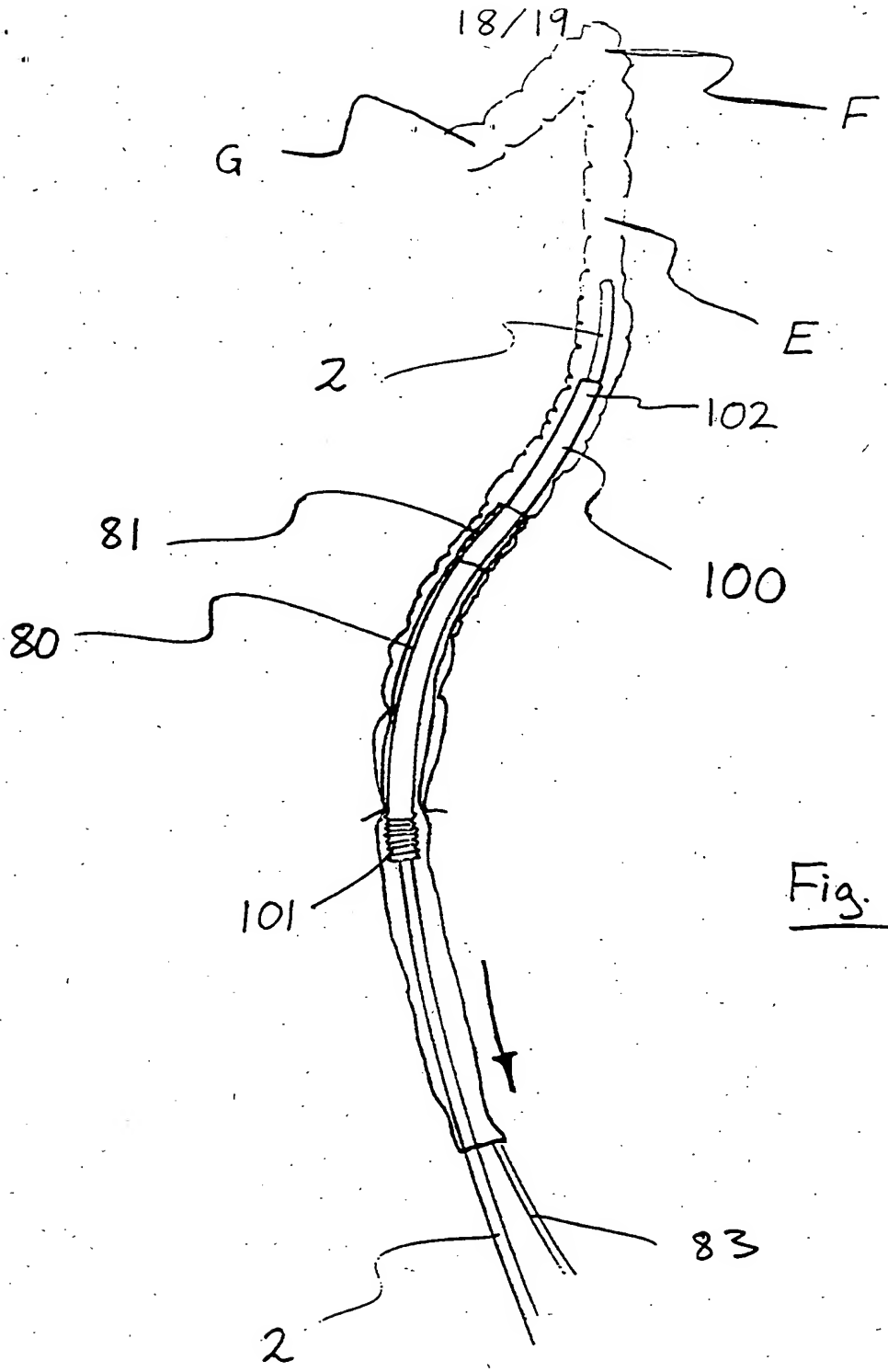

Fig. 19

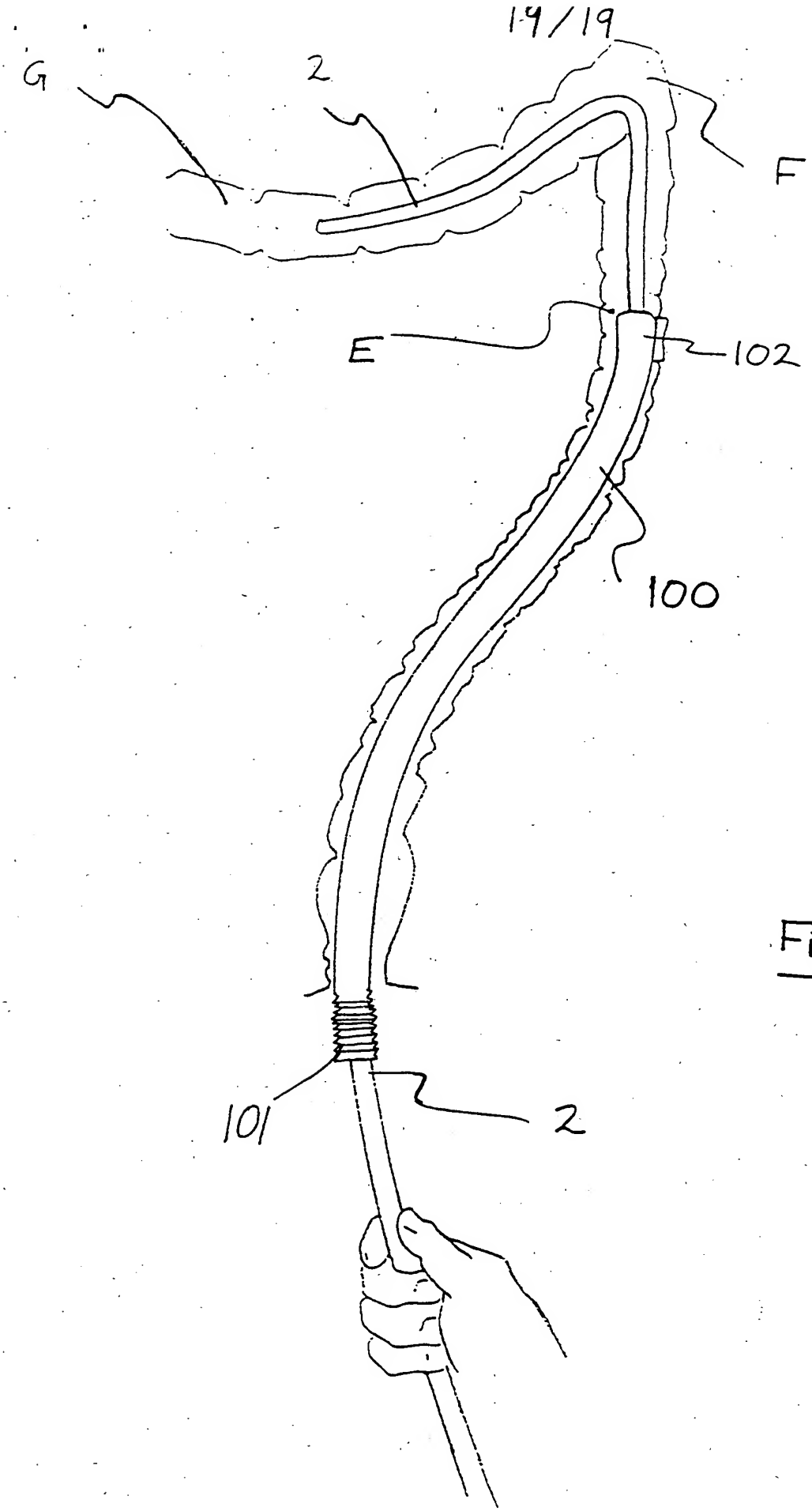

Fig. 20